

**Federal Policy Options to  
Contain Medicaid Drug Costs**

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**For the Center for American Progress Panel Discussion:**

**MEDICAID: WHAT'S DRIVING COSTS AND WHAT TO DO ABOUT IT**

**June 8, 2005**

## **Federal Policy Options to Contain Medicaid Drug Costs**

Spending on prescription drugs is a major cost driver in the health care system generally and a particular burden for state Medicaid programs that provide vital health care coverage for many of the nation's most medically vulnerable individuals. Medicaid accounts for nearly one in five dollars spent on prescription drugs in the United States, and nearly half of those expenditures are for low-income seniors who are dually eligible for Medicare and Medicaid ("dual eligibles").<sup>1</sup> In recent years, almost all states have worked to implement pharmacy cost containment measures that preserve access to the vital drug therapies upon which Medicaid beneficiaries rely. The federal government has been generally supportive of state efforts, but has initiated few of its own. More could be done at the federal level to assist states and promote efficiencies across the country. This paper discusses federal options that would assist states to (a) purchase prescription drugs more effectively at the retail level, (b) maximize manufacturer rebates, (c) reduce the ongoing cost burden on states of the new Medicare drug benefit, and (d) promote the delivery of evidence-based, cost-effective pharmaceutical care.

### **Background**

Since FY 2004, state revenue collections have been slowly recovering from the most severe fiscal downturn in 60 years.<sup>2</sup> Despite improving economic conditions, state revenue remains below its 2000 peak (after adjusting for inflation and population

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<sup>1</sup> Brian Bruen and Arunabh Ghosh, "Medicaid Prescription Drug Spending and Use," June 2004, Washington, D.C., Kaiser Commission on Medicaid and the Uninsured, Pub. No. 7111.

<sup>2</sup> National Governors Association, National Association of State Budget Officers, "The Fiscal Survey of States," December 2004.

growth)<sup>3</sup> and budgets continue to be strained by Medicaid spending growth that exceeds revenue growth in many states. The long-term outlook offers little hope for a Medicaid spending reprieve. Both the Congressional Budget Office and the Centers for Medicare and Medicaid Services (CMS) project that over the next decade, federal Medicaid spending will grow at an average annual rate of more than eight percent.<sup>4</sup>

Over the past four years, state Medicaid officials have cited prescription drugs as one of the top three Medicaid cost drivers along with enrollment growth and rising medical care costs generally.<sup>5</sup> Indeed, prescription drugs are one of the fastest growing Medicaid service categories; expenditures doubled between 1998 and 2002, and have quadrupled since 1992. As a result, prescription drugs grew from 8 percent of total Medicaid expenditures in 1998 to over 11 percent in 2002.<sup>6</sup> In CY 2003, Medicaid spending for prescription drugs grew by 17.5 percent, similar to growth in the previous two years.<sup>7</sup> A combination of factors drove this growth including increases in the number of beneficiaries, drug utilization growth (i.e., more prescriptions per person), the substitution of newer, more costly drugs for older, less expensive drugs, and increases in drug prices. Medicaid drug spending growth is projected to decelerate to 7.1 percent in CY 2004 due in large part to state drug cost containment efforts.<sup>8</sup> While this is below the

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<sup>3</sup> D. Boyd et al., "State and Local Governments Face Continued Fiscal Pressure," The Rockefeller Institute of Government Fiscal Studies Program, January 2005.

<sup>4</sup> Congressional Budget Office, "The Budget and Economic Outlook: Fiscal Years 2006 to 2015," January 2005, and Stephen Heffler, et al., "U.S. Health Spending Projections for 2004 – 2014," *Health Affairs Web Exclusive*, February 23, 2005.

<sup>5</sup> V. Smith et al., "The Continuing Medicaid Budget Challenge: State Medicaid Spending Growth and Cost Containment in Fiscal Years 2004 and 2005," October 2004, Washington, D.C., Kaiser Commission on Medicaid and the Uninsured, Pub. No. 7190.

<sup>6</sup> B. Bruen and A. Ghosh, June 2004.

<sup>7</sup> C. Smith et al., "Health Spending Growth Slows in 2003," *Health Affairs*, 24, no. 1 (2005): 185-194.

<sup>8</sup> S. Heffler, et al., "U.S. Health Spending Projections for 2004 – 2014," *Health Affairs Web Exclusive*, February 23, 2005.

overall rate of drug cost growth (11.9 percent), it is still high and more can and should be done.

Net Medicaid spending on drugs reflects payments made to pharmacies at the retail level and rebates paid to states by manufacturers. States have considerable discretion in setting retail pharmacy payments, which must recognize both drug costs and a dispensing fee. For sole-source brand name drugs, states must pay the lower of the pharmacy's "usual and customary charge" to the public or the drug's "estimated acquisition cost" (EAC) plus a dispensing fee. Each state determines its own EAC formula (usually based on the "average wholesale price"), and sets its own dispensing fee. The EAC and the dispensing fee amount vary significantly from state to state. Generic products are often subject to different pricing rules. Some are subject to a "federal upper limit"(FUL) set by CMS for drugs with generic equivalents that meet certain criteria. Most states have also chosen to set their own "maximum allowable cost" prices for generics, which can be lower than the FUL and sometimes apply to generics not covered by the FUL.

States struggling with the rapid growth of Medicaid drug spending hoped that a new Medicare pharmacy benefit would provide significant state fiscal relief. Instead, to help finance the new drug benefit that begins in January 2006, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003<sup>9</sup> (the "MMA") requires CMS to recoup from states much of the savings that states would otherwise have realized from shifting prescription drug coverage for dual eligibles to Medicare. This recoupment is commonly referred to as the "Clawback." The MMA provides for a ten-year partial

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<sup>9</sup> Pub. L. 108-173

phase-down of the Clawback amount starting at 90 percent in 2006 (in other words, allowing the states to retain 10 percent of the calculated savings), and decreasing to 75 percent in 2015 and thereafter. There is, however, no end to the state Clawback obligation. In practice, many states believe the Clawback formula is flawed and may result in a negative state fiscal impact rather than a savings.

## **State Actions to Control Medicaid Prescription Drug Spending**

### **Growth**

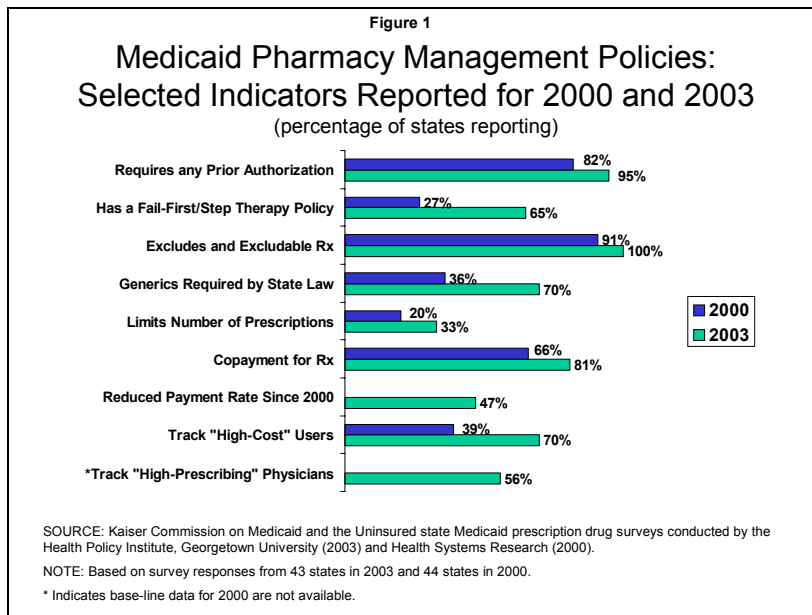
In almost all states, prescription drugs have been the focus of ongoing, sustained efforts to slow multi-year double-digit cost growth. In 2004, 47 states and the District of Columbia reported implementing prescription drug cost containment measures and 43 reported plans to take additional steps in 2005.<sup>10</sup> These measures include imposing prior authorization requirements and step therapy protocols, limiting the number of brand prescriptions per month, new or higher copay requirements and reductions in retail pharmacy reimbursement policies. States have also hoped to better control drug utilization by implementing disease management and case management programs and provider profiling and counter-detailing initiatives.

Figure 1 below illustrates the results of a 2003 survey of state Medicaid programs comparing drug cost containment measures reported in 2003 to those reported in 2000.<sup>11</sup> Among other things, the survey results demonstrate the widespread adoption of multiple policies over a relatively short period of time.

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<sup>10</sup> V. Smith et al, October 2004.

<sup>11</sup> Jeffrey S. Crowley et al, *"Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey, 2003,"* December 2003, Washington, D.C., Kaiser Commission on Medicaid and the Uninsured, Pub. No. 4164.



A rapidly growing number of states have also chosen to implement preferred drug lists (PDLs) and negotiate for supplemental rebates from pharmaceutical manufacturers: 37 states have implemented or plan to implement a PDL and 33 states currently receive supplemental rebates.<sup>12</sup> More recently, a number of states have joined multi-state pooling arrangements to increase their market leverage to maximize supplemental rebates. In April 2004, Health and Human Services (HHS) Secretary Tommy Thompson approved plans by five states (Michigan, Vermont, New Hampshire, Alaska, and Nevada) to pool their collective purchasing power and Minnesota, Hawaii, Montana, Kentucky and Tennessee subsequently joined this pool. In May 2005, HHS Secretary Mike Leavitt

<sup>12</sup> Data compiled by the National Conference of State Legislatures and accessed at <http://www.ncsl.org/programs/health/medicaidrx.htm>; Testimony of Dennis Smith, Director of the Center for Medicaid and State Operations, Centers for Medicare and Medicaid Services, presented at a hearing on "Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much," before the Subcommittee on Oversight and Investigations, Energy and Commerce Committee, U.S. House of Representatives, December 7, 2004.

approved a new multi-state purchasing pool comprised of Louisiana, Maryland and West Virginia. Over the next year, it is likely that more states will join a multi-state purchasing pool motivated, in part, by the January 2006 implementation of the new Medicare drug benefit that will cut in half *direct* state Medicaid pharmacy expenditures. (States will continue to *indirectly* pay for drug coverage for dual eligibles through the Clawback.) Since greater volume translates to greater leverage to negotiate supplemental rebates, states may be forced to join multi-state pools just to retain their current level of supplemental rebates after 2006.

States and the federal government jointly fund Medicaid, and therefore rising Medicaid prescription drug costs also have adverse fiscal consequences for the federal budget. In recent years, CMS has taken some steps to assist and support states with their pharmacy cost containment activities. In 2002, CMS issued guidance to states supporting supplemental rebate programs.<sup>13</sup> In 2004, CMS approved requests from a number of states to form a multi-state purchasing pool. Also, CMS identified selected best practices for Medicaid pharmacy savings and offered assistance to those states that have not implemented these effective mechanisms.<sup>14</sup> While these efforts are laudable, more could be done at the federal level to assist states and promote efficiencies across the country.

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<sup>13</sup> Dear State Medicaid Director letter dated September 18, 2002 accessed at <http://www.cms.hhs.gov/states/letters/smd91802.pdf>.

<sup>14</sup> Included were (1) the long-standing practice of many states to prior authorize brand name equivalents to generic drugs, (2) negotiation of manufacturer supplemental rebates, (3) implementation of disease management programs, and (4) efforts to promote e-prescribing. *Safe and Effective Approaches to Lowering State Prescription Drug Costs: Best Practices Among State Medicaid Drug Programs (9/9/04)*, [www.cms.hhs.gov/medicaid/drugs/strategies.pdf](http://www.cms.hhs.gov/medicaid/drugs/strategies.pdf).

## **Prudent Purchasing at the Retail Level**

States largely operate “in the dark” in setting drug cost reimbursement without access to the actual drug acquisition costs paid by pharmacies. States typically cover over 50,000 National Drug Codes – each with its own price that can change unpredictably. It is therefore a challenge to find adequate current information to set drug reimbursement rates at levels that fairly compensate pharmacies without overpaying.

While states often set their own maximum allowable cost prices for generics and selected brand name drugs, they rely on national firms to supply electronic drug pricing files for most drugs. States then determine the pharmacy reimbursement rate by taking a discount from the reported “Average Wholesale Price” (AWP), or by assigning a mark-up to the reported “Wholesale Acquisition Cost” (WAC), and adding a dispensing fee.<sup>15</sup>

Reimbursement formulas vary significantly from state to state. Similar pricing policies are used by private sector plans, but their rates are often lower than Medicaid.

Recent reports by the HHS Office of Inspector General (OIG) have highlighted the millions of dollars lost to states and the federal government each year due to Medicaid overpricing.<sup>16</sup> One of the main culprits for the overpricing is the AWP. The AWP is essentially a nationally published list price (largely set by manufacturers) that bears little resemblance to a pharmacy’s actual acquisition cost. Manufacturers may even raise an AWP to artificially create a larger *spread* between AWP and actual acquisition cost to

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<sup>15</sup> For example, a state may reimburse a pharmacy at AWP minus 10 to 15 percent plus a fixed dispensing fee of \$3 to \$5.

<sup>16</sup> Department of Health and Human Services, Office of Inspector General, “*Variation in State Medicaid Drug Prices*,” September 2004, OEI-05-02-00681; see also, testimony presented at hearing on “*Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much*” before the Subcommittee on Oversight and Investigations, Energy and Commerce Committee, U.S. House of Representatives, December 7, 2004.

increase retail pharmacy profits, thereby making the product more attractive to pharmacies. Widely viewed as inflated and flawed, the AWP was recently abandoned by Medicare Part B (in the MMA) in favor a new “Average Sales Price” (ASP) methodology.

Federal policy could assist states in becoming more prudent purchasers at the retail pharmacy level. Proposals 1 through 3 below present alternatives that would each provide states with better information to set retail pharmacy reimbursement policies by (1) providing a new source of drug pricing data (ASPs), (2) improving the accuracy and reliability of the drug pricing data most commonly used today (AWPs), or (3) releasing (on a limited basis) drug pricing data that is currently confidential (AMPs). The fourth proposal calls for improvements in the current federal FUL program that establishes prices for certain multi-source drugs.

***1. Provide states with accurate and timely ASPs for Medicaid covered drugs.***

For drugs covered under Medicare Part B,<sup>17</sup> the MMA requires Medicare to use an ASP plus 6 percent payment methodology. “ASP” is the weighted average of all non-federal sales from manufacturers to wholesalers (net of chargebacks, discounts, rebates, and other benefits tied to the purchase of the drug product), and is based on quarterly pricing data supplied to CMS by drug manufacturers. While some critics argue that the ASP does not accurately reflect a retail pharmacy’s actual acquisition cost, the ASP is likely a better starting point for estimating that cost than the AWP.

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<sup>17</sup> Part B drugs include drugs furnished incident to a physician’s service, durable medical equipment drugs, and other drugs covered by statute, such as oral immunosuppressive, cancer, and antinausea drugs.

Moving to an ASP methodology in Medicaid, however, would be a significant and costly undertaking that would be difficult for states to accomplish on their own. To enable all states to benefit from this methodology, the federal government (acting through CMS) would need to handle the data collection and timely pricing of the over 50,000 National Drug Codes commonly covered by state Medicaid programs. (Currently, CMS collects manufacturer data on only 5,700 National Drug Codes to price 550 Part B drugs.) States would also need to rely upon CMS for timely pricing information on new drugs entering the market and for manufacturer price adjustments that occur from time to time. (Currently, CMS provides only quarterly updates for Part B drugs subject to ASP pricing.) Ultimately, the benefit to states of moving to an ASP methodology would depend heavily upon the effectiveness of CMS in calculating and reporting the ASP prices.

President Bush's 2006 federal budget proposal would *require* states to adopt an ASP plus 6 percent payment methodology (consistent with Medicare Part B) and estimates federal savings of \$542 million in 2006 and \$5.4 billion over five years. (The proposal, however, does not address whether CMS would be responsible for the accurate and timely calculation of the ASP prices.) While states would benefit from accurate and reliable ASP pricing information to use in place of the current inflated and artificial AWP prices, it would likely be advantageous to allow states to retain some flexibility to revise payment methodologies as the need for improvements becomes obvious or necessary over time and to respond to local state conditions.

***2. Incentivize manufacturers to set more realistic AWP prices by linking them to the statutory Medicaid rebate formula.***

Created by the Omnibus Budget Reconciliation Act of 1990, the Medicaid Drug Rebate Program requires a drug manufacturer to enter into a national rebate agreement with the secretary of HHS in order for that manufacturer's drugs to be covered under Medicaid. CMS calculates rebate amounts using a statutory formula based on the "average manufacturer price" (AMP), defined as the average price paid by wholesalers for drugs distributed to the retail class of trade. Using the same benchmark (AWP) for both the rebate formula (instead of AMP) and pharmacy reimbursement policy would provide an incentive for manufacturers to establish lower, more realistic AWP and reduce the ability of manufacturers to "game the spread" between AWP and the actual acquisition cost. Another way to achieve a similar result would be to apply a rebate penalty if the difference between AWP and AMP exceeded 20 percent. Medicare Part B uses a similar technique to validate ASPs by comparing ASP to AMP. By law, AMPs are confidential and therefore state Medicaid agencies are unable to implement this type of reasonableness test for AWP on their own.

***3. Change federal law to allow the release of AMP information to the states.***

The AMP data provided to CMS by drug manufacturers to support the Medicaid Drug Rebate Program is likely the most accurate drug pricing data currently available to CMS for non-Medicare Part B drugs. A limited disclosure of this data to states could be required by federal law to help states set drug cost reimbursement at appropriate levels, as has been recommended by the Department of Health and Human Services Office of the Inspector General.<sup>18</sup>

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<sup>18</sup> Department of Health and Human Services, Office of Inspector General, "Variation in State Medicaid Drug Prices," September 2004, OEI-05-02-00681.

**4. Improve the process for placing multi-source drugs on the “Federal Upper Limit” (FUL) list.**

The FUL program, administered by CMS, limits Medicaid payments for drugs with generic equivalents that meet certain criteria: there must be three therapeutically equivalent drug products and CMS must verify that there are at least three suppliers. If these criteria are met, the FUL is set at 150 percent of the published AWP price for the least costly therapeutically equivalent product. This formula implemented in the late 1980s should be revised to reflect actual market pricing trends and to use strategies based on AMP markups. Also, in a recent OIG HHS report, CMS was criticized for failing to add many qualified drugs to the list and adding others too slowly.<sup>19</sup> As the OIG recommended, CMS at a minimum could focus its resources on high-volume brand name drugs that are coming off patent that could be placed on the FUL list and result in significant Medicaid savings.

**Maximizing Manufacturer Rebates**

The methodology for the required rebate that drug manufacturers must pay to participate in Medicaid has not been modified for over 12 years, despite rapid growth in prices and costs (see Table 1 below.) This has forced a growing number of states to seek supplemental rebates, which can sometimes be difficult for a state to enact. Proposals 1 through 3 below describe federal policy changes to the current rebate formula that would increase rebate revenues to states. The fourth proposal calls for improvements in the

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<sup>19</sup> Ibid. See also, testimony of George M. Reeb, Assistant Inspector General, presented at hearing on “Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much” before the Subcommittee on Oversight and Investigations, Energy and Commerce Committee, U.S. House of Representatives, December 7, 2004.

administration of the rebate program and the fifth proposal raises a concern with the rebate formula modification proposed in the Bush administration's 2006 budget proposal.

Table 1.

Type of Drug	Federal Rebate Formulas <sup>20</sup>		
Generic Drugs Non-Innovator	Average Manufacturer Price (AMP) times 11%		
Brand Name Drugs Single Source & Innovator	Basic Rebate (Step 1) Greater of: <ul style="list-style-type: none"> <li>AMP times 15.1%</li> <li>AMP minus Best Price</li> </ul>	Additional Rebate (Step 2) Rebate Penalty, if AMP price increases exceed the CPI-U	Total Rebate = Step 1 + Step 2

**1. Increase the minimum federally required rebate.**

When the new Medicare prescription drug benefit is implemented in 2006, direct state Medicaid drug expenditures will be cut in half. The lost prescription volume will likely decrease the market leverage that states have to negotiate supplemental rebates. An updated minimum rebate would help states compensate for the loss of market leverage and ensure that all states, as well as the federal government, pay a fair price for prescription drugs covered by Medicaid. The National Governors Association, on a bipartisan basis, supports increasing the rebate.<sup>21</sup>

**2. Implement an indexed best price calculation in the rebate formula.**

To discourage manufacturers from raising AMP amounts, the rebate formula contains a penalty for AMP price increases that exceed the consumer price index for urban consumers (CPI-U). The penalty is equal to the amount that AMP increased over and above the CPI-U. A similar penalty, however, is not applied for increases in the "best

<sup>20</sup> Centers for Medicare & Medicaid Services, Medicaid Drug Rebate Program, Operational Training Guide, September 2001.

<sup>21</sup> National Governors Association. 2004. EC-3. Medicaid Drug Rebate Program. [http://www.nga.org/nga/legislativeUpdate/1,1169,C\\_POLICY\\_POSITION^D\\_3716,00.html](http://www.nga.org/nga/legislativeUpdate/1,1169,C_POLICY_POSITION^D_3716,00.html)

price” component of the formula even though drug manufacturers have consistently increased best price in excess of the CPI-U since the inception of the Medicaid Drug Rebate Program.<sup>22</sup> Indexing the best price component of the rebate calculation would therefore increase drug rebates for many brand name drugs.

***3. Add an inflation-related adjustment to the federal rebate formula for generic drugs.***

Unlike the current rebate formula for brand name drugs, the current formula for generic drugs contains no penalty adjustment for AMP price increases that exceed the CPI-U. Adding such a penalty could increase rebate revenues to states, but would also discourage generic manufacturers from increasing prices in excess of the rate of inflation.

***4. Implement systematic oversight of self-reported manufacturer pricing data to assure the accuracy of Medicaid drug rebates.***

Currently, the calculation of Medicaid drug rebates relies upon self-reported AMP and “best price” data supplied to CMS by drug manufacturers. In recent years, a number of drug manufacturers have agreed to pay millions of dollars in legal settlements to resolve allegations involving the underpayment of Medicaid rebates arising from the failure to properly report best price. A recent report from the Government Accountability Office (GAO) also found that current rebate program oversight by CMS does not assure that manufacturer-reported drug prices are consistent with applicable laws and program policies.<sup>23</sup> Consistent with GAO recommendations, CMS should implement a plan to systematically scrutinize AMP and best price data reported by manufacturers to enforce the accurate payment of Medicaid drug rebates to states.

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<sup>22</sup> Department of Health and Human Services, Office of the Inspector General, Cost-Saver Handbook, “2004 Red Book.”

<sup>23</sup> United States Government Accountability Office, “Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States,” February 2005, GAO-05-102.

**5. Maintain the “best price” calculation in the current rebate formula.**

The president’s 2006 budget recommendations propose to eliminate the best price requirement from the Medicaid drug rebate formula and replace it with a budget neutral flat rebate to allow private purchasers to negotiate lower prices from manufacturers. Flat rebates, however, could dramatically affect the structure of state PDLs and the savings they currently generate for states. PDL savings are based on shifting utilization to those drugs with the lowest net cost after federal and supplemental rebates. If federal rebates change, preferred products may no longer be cost effective compared to non-preferred drugs within a class and cost increases could result.

**Comment [CHSRP1]:** A question: aren't you proposing to increase the federal rebate in option 1 etc? If savings are achieved by the flat rebate, what's the problem?

**Impact of the Medicare Drug Benefit**

When the Medicare prescription drug benefit takes effect in January 2006, state Medicaid programs will no longer provide drug coverage for dual eligibles but will continue to help finance a substantial portion of the new Medicare drug coverage through the Clawback. States will therefore lose the ability to manage the prescription drug benefit for duals, even as they must continue to finance it. The Clawback formula includes future annual adjustments based upon per capita spending growth for the Medicare drug benefit. Thus, states have a direct interest in how the Medicare drug program is managed: higher per capita growth in Medicare drug spending means a larger Clawback obligation for states.

The first two proposals below describe steps that the federal government could take to constrain the growth in per capita Medicare drug spending, and thereby directly benefit states by moderating future growth in the Clawback. Proposals 3 and 4 suggest that the

MMA should be amended to eventually require the federal government to assume the full financial cost of the Part D benefit for dual eligibles.

***1. Eliminate the MMA prohibition preventing CMS from negotiating for better pharmaceutical pricing.***

Section 1860D-11(i) of the Social Security Act, as added by the MMA, bars the secretary of HHS from interfering with the negotiations between drug manufacturers and pharmacies and sponsors of prescription drug plans, or from requiring a particular formulary or price structure for covered Part D drugs. The CBO has estimated that there would be negligible savings if this provision was struck,<sup>24</sup> but others disagree. They point to the substantial discounts obtained by other countries who negotiate on behalf of their citizens and by the U.S. Veteran's Administration as compelling evidence of the savings potential for Medicare.<sup>25</sup> Even if HHS chose not to exercise its authority to negotiate for better prices (or exercised its authority poorly), the repeal of Section 1860D-11(i) may, nevertheless, promote better drug pricing for Medicare by changing the context in which drug pricing decisions are made – pharmaceutical manufacturers may be more likely to exercise restraint in their pricing decisions to avoid provoking a response from HHS.

***2. Hold states harmless from the cost of future changes to the Medicare drug benefit that have the effect of driving up the rate of Medicare drug spending growth.***

State officials are all too familiar with the phenomenon of special interest groups advocating, often successfully, at the state level for state insurance laws mandating specific benefits. The likelihood of this happening at the federal level with regard to the new Medicare drug benefit is surely high. Because the Clawback calculation is based on

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<sup>24</sup> CBO Letter dated January 23, 2004 to the Honorable William H. Frist, M.D. accessed at <http://www.cbo.gov/showdoc.cfm?index=4986&sequence=0>.

<sup>25</sup> See Families U.S.A., *Another Hole in the Medicare Drug Benefit*, March 2004 accessed at [http://www.familiesusa.org/site/DocServer/Another\\_Hole.pdf?docID=2885](http://www.familiesusa.org/site/DocServer/Another_Hole.pdf?docID=2885).

a comprehensive Medicaid drug benefit that is likely to be more generous than the basic Medicare benefit offered in 2006, states should not be forced to pay twice if future federal actions are taken to enhance the Medicare benefit in any way that would increase costs to states under the Clawback formula. For example, many states exclude certain classes of drugs (such as mental health drugs) from their PDLs and prior authorization programs. The Clawback obligation for these states will include the cost of this open access policy even though dual eligibles may not have the same open access to these drugs under the new Medicare benefit. If a mandate for open access to certain drugs or drug classes is added to the Medicare benefit in the future, the cost of that mandate could increase the cost of the Clawback obligation to states forcing some states to pay for open access a second time.

***3. Eliminate the MMA exclusion of certain drug classes from the Medicare Part D drug benefit.***

The MMA excludes coverage for a number of drug classes that are optional but commonly covered under Medicaid, including over-the-counter drugs, barbiturates used for seizures and benzodiazepines for anxiety. According to a recent study, more than half of dually eligible nursing home residents will be affected by the excluded drugs provision in the law because they are currently receiving at least one medication that will be excluded from coverage under Medicare Part D.<sup>26</sup> The exclusion of benzodiazepines and barbiturates has been identified as a particular concern due to their widespread use in elderly populations and the potential for therapeutic destabilization if discontinued.

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<sup>26</sup> R. Stefancacci, “*The Cost of Being Excluded: Impact of Excluded Medications under Medicare Part D on Dually Eligible Nursing Home Residents*,” Health Policy Institute at the University of the Sciences in Philadelphia, February 16, 2005, citing an analysis conducted by Omnicare, Inc., a national long-term care pharmacy provider.

For dual eligibles who need one of these excluded medications after January 1, 2006, they must either turn to Medicaid for coverage or prescribers will be forced to use alternative medications that will be less effective, more costly and, for some patients, even toxic.<sup>27</sup> Thus, states will either bear the cost of providing the excluded drugs or incur greater nursing home or other costs due to adverse health consequences. For these reasons, the MMA should be amended to provide coverage for these excluded drug classes, at least for dual eligibles and other persons receiving Part D low-income subsidies.

***4. Amend the MMA to phase out the Clawback obligation completely.***

The MMA currently provides for a ten-year partial phase-down of the Clawback amount starting at 90 percent in 2006 and decreasing to 75 percent in 2015 and thereafter. The timing of the phase-down could be accelerated or continued beyond 2015 with the goal of completely eliminating this unprecedented Medicare financing mechanism and fiscal obligation on states.

**Comparative Effectiveness**

Advances in technology are transforming the delivery of health care in the United States but are also the most important long-term driver of health care costs. While the growth in prescription drug costs has recently moderated, this could turn out to be a temporary “lull” rather than a long-term trend due to technology advances.<sup>28</sup> Efforts to assist states

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<sup>27</sup>Ibid.

<sup>28</sup> According to a recent study from the Tufts Center for Study of Drug Development, advances in biotechnology research and development will result in nearly 50 new biotech medicines receiving market approval from the U.S. Food and Drug Administration. Tufts Center for Study of Drug Development, March 7, 2005 press release, “*Biotechnology Advance have Improved R&D Success Rates, According to Tufts CSDD.*”

to become more prudent Medicaid purchasers must therefore go beyond improved pricing strategies (such as changing from an AWP to an ASP-based pricing system), to also include the creation of new evidence-based tools that will assist states in appropriately controlling utilization.

After four years of widespread, continuous efforts to cut Medicaid spending growth, an increasing number of states are turning to evidence-based disease management and case management programs with the hope that improving the quality of care will result in lower long-term costs for care. In the pharmacy arena, a consortium of 15 organizations, including 13 states, has formed to create the Drug Effectiveness Review Project (DERP) whose purpose is to carry out systematic reviews of drug classes to inform state drug coverage decisions, usually in connection with a state's Medicaid PDL. These systematic reviews, conducted by Evidence-based Practice Centers (mostly university-based), array, evaluate and summarize the aggregate results of published and unpublished studies pertaining to the drug class under review. The DERP reports its findings concerning safety and effectiveness, but does not make policy or coverage recommendations. By September 2004, the DERP had completed twelve reviews and a number of review updates and had ten reviews in progress.

At the federal level, interest in evidence-based health care management continues to grow as well. Most recently, Section 1013 of the MMA requires the HHS secretary to set priorities and target areas where evidence is needed to improve the quality, effectiveness and efficiency of health care provided by Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP). The HHS secretary is directed to:

“ . . . conduct and support research to meet the priorities and requests for scientific evidence and information identified by such programs with respect to—  
    (i) the outcomes, comparative clinical effectiveness, and appropriateness of health care items and services (including prescription drugs); and  
    (ii) strategies for improving the efficiency and effectiveness of such programs, including the ways in which such items and services are organized, managed, and delivered under such programs.”

The MMA language recognizes the need to synthesize existing scientific research to inform policy and coverage decisions in public programs, but also recognizes that there are gaps in the current research base. In a recent article, the director of the Agency for Healthcare Research and Quality summarized the challenge as follows:

“For many policy issues, there is too little evidence to be of much help. The challenge now is to ensure that clinicians and policymakers can easily find out what we do know, support research to answer what we do not know, and promote change in the health care system that will continue to narrow the gap between what we know and what we do.”<sup>29</sup>

State Medicaid programs and beneficiaries would benefit greatly from an expansion in the base of evidence-based research. In particular, this information could be used to help further define “smart” PDLs rather than states relying too heavily on price considerations when making PDL coverage policies. Few if any states, however, are in a position, on their own, to undertake the needed research efforts. Clearly, it is more appropriate for the federal government to call upon its considerable technical, policy and fiscal resources to tackle this challenge for the benefit of all federal, state and private health care payers, purchasers and patients. While the federal government has taken steps in this direction, it has not gone far enough in light of the enormity of the health care fiscal challenges that loom ahead, and therefore the proposal below calls upon the federal government to commit greater resources to this effort.

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<sup>29</sup> Carolyn M. Clancy and Kelly Cronin, “Evidence-Based Decision Making: Global Evidence, Local Decisions,” *Health Affairs*, 24, no. 1 (2005): 161.

***Commit greater federal resources and leverage greater private resources to carry out the purposes of Section 1013 of the MMA.***

Federal, state and private efforts in recent years have expanded the information base available to policymakers making health policy and coverage decisions, but a greater investment is needed to keep up with the pace of technological change. While the MMA authorized \$50 million in FY 2004 to carry out Section 1013, only \$15 million was actually budgeted for this effort in 2005 and the president's 2006 budget maintains funding at the \$15 million level. At a minimum, funding to carry out Section 1013 should be increased to the amount authorized by the MMA. Greater investments would likely lead to greater cost containment benefits in the future.

**Conclusion**

Medicaid spending growth is straining both state and federal budgets and growth in prescription drug spending continues to be a major culprit in that overall growth. While states have made great strides in reforming their prescription drug programs and have achieved significant savings, more could be done at the federal level to assist states. The federal government can help states obtain better drug pricing information and can also assist states in maximizing manufacturer rebates by adjusting the current rebate formula and better enforcing rebate program requirements. By ensuring the cost-effective management of the Medicare Part D drug benefit, the federal government can also mitigate the future growth of the states' Clawback obligations. Finally, like all payers, Medicaid's greatest hope for long-term cost containment benefits lies in the ability to manage drug utilization using evidenced-based tools. The federal government can play an instrumental role in supporting research efforts that will fill in the gaps in the existing

research base and by supporting efforts to synthesize and analyze currently available research to better inform coverage decisions.